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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/521,086	03/07/2000	Miladin P. Lazarov	11699-002001	9173

26161 7590 01/27/2003

FISH & RICHARDSON PC
225 FRANKLIN ST
BOSTON, MA 02110

[REDACTED] EXAMINER

PAULRAJ, CHRISTOPHER

ART UNIT	PAPER NUMBER
1773	/6

DATE MAILED: 01/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/521,086	LAZAROV ET AL.	
	Examiner	Art Unit	
	Christopher G. Paulraj	1773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 28 October 2002.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-3,5-17 and 19 is/are pending in the application.
- 4a) Of the above claim(s) 12-16 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-3,5-11,17 and 19 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|--|
| <input type="checkbox"/> Notice of References Cited (PTO-892) | <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The request filed on October 28, 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/521,086 is acceptable and a CPA has been established. An action on the CPA follows.
2. Claims 12-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 5.
3. Applicant's arguments with respect to claims 1-3, 5-11, 17, and 19 have been considered but are moot in view of the new ground(s) of rejection. As explained in further detail below, the process limitation added in the amendment does not distinguish the claimed product from the applied reference.

Claim Rejections - 35 USC § 112

4. Claims 5, 6, 10, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claim 5 appears to contain a typographical error. Instead of a thickness between 0 and 5 μm , it recited 9 and 5 μm . Claim 6, reciting a specific resistance between 10 and 10 $\mu\Omega\cdot\text{cm}$, also appears to be in error.
6. Claim 10 recites an alternative limitation using improper Markush group terminology. Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, is recited as "wherein R is a

material selected from the group consisting of A, B, C and D." See Ex parte Markush, 1925 C.D. 126 (Comm'r Pat. 1925). It is improper to use the term "comprising" instead of "consisting of." Ex parte Dotter, 12 USPQ 382 (Bd. App. 1931). Another acceptable form is recited as "wherein R is A, B, C or D." See MPEP 2173.05(h).

7. Claim 19 is still in improper dependent form. A dependent claim cannot incorporate different features from two different sets of claims. See MPEP 608.01(n).

Claim Rejections - 35 USC § 102

8. Claims 1, 3, 5, 6, 7, 8, 11, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Davidson (U.S. Patent 5,496,359).

Davidson discloses zirconium oxide and zirconium nitride coated biocompatible leads, in which the coating is applied by physical or chemical vapor deposition (abstract). The coated surfaces may be further coated with other compositions such as heparin and protein to further enhance biocompatibility (col. 4, lines 20-25). The coatings can have a thickness of 3 to 6 microns (col. 8, lines 26). The claimed specific resistance (claim 6) is considered to be met because the same materials are used. The article may be used as stents (col. 3, line 21).

The amended claims add a process limitation. It is the examiner's position that the article disclosed by Davidson is identical to or only slightly different than the claimed article prepared by the method of the claim(s), because both contain the same materials. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the

same as or an obvious variation from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). The burden has been shifted to the applicant to show unobvious differences between the claimed product and the prior art product. *In re Marosi*, 218 USPQ 289, 292 (Fed. Cir. 1983). The Davidson reference either anticipated or strongly suggested the claimed subject matter. It is noted that if the applicant intends to rely on Examples in the specification or in a submitted Declaration to show non-obviousness, the applicant should clearly state how the Examples of the present invention are commensurate in scope with the claims and how the Comparative Examples are commensurate in scope with the Davidson reference.

Applicants argue that Davidson implies that dense coatings are critical and that applicants recited pressure of 10^{-4} to 10^{-2} mbar would result in porous coatings. However, the terms dense and porous are relative terms. What may be considered to be "dense" by Davidson, may nevertheless be porous enough to meet the instant claim limitations. Applicants need to submit evidence in declaration form showing that the pressures recited in the instant claims would result in a patentably distinct product than that of Davidson.

Furthermore, Applicants have not sufficiently shown that the "standard physical or chemical vapor deposition methods" disclosed by Davidson (col. 11, lines 15-20) would use lower pressures than the claimed range. Applicants have submitted pages from the instruction manual for the Temescal Electronic Beam Source, which shows that the vacuum chamber is evacuated to 1×10^{-4} , (0.1 micron or less). This converts to pressure of 1.33×10^{-4} mbar, which falls within the claimed range. Applicants have not submitted any evidence in support of their argument that pressure while metalization is taking place would

be lower than the starting pressure. Applicants have also not submitted any evidence showing that the pressure disclosed in the instruction manual is considered "standard" in the art.

Claim Rejections - 35 USC § 103

9. Claims 1-3, 5-8, 10-11, 17, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lazarov et al. (WO96/25960) in view of Davidson. U.S. Patent 6,110,204 is used to serve as an English translation of the WO document.

Lazarov et al. discloses implants for use in the human body, where a substrate is coated with a material which contains chemical compounds between one or more metals (M) of group IV A of the periodic system (Ti, Zr, and Hf), with 2 to 45 % of the volume of the coating being formed by voids. The formula of Mn_xO_y recited in the abstract meets the requirements of claim 3. The coating has a preferable surface resistance of 30 to 30000 $\mu\Omega.cm$ (col. 3, lines 25). The underlying substrate can be gold or tantalum (claims 7,14). The deposition is done at gas pressures that can range from 10^{-2} to 10^{-4} hPa (col. 7, lines 15-40). The implant can be used as stents (col. 1, line 10).

Lazarov et al. does not specifically teach that a protein, peptide, and/or saccharide containing substance can be applied onto the group IV A metal layer. However, in light of what Davidson teaches, one skilled in the art would have found it obvious to apply such a substance such as heparin onto the metal layer. The motivation for doing so would have been to improve the biocompatibility of the article.



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TC 1700

Attorney's Docket No.: 11699-002001

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1773

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Miladin P. Lazarov et al.
Serial No. : 09/521,086
Filed : March 7, 2000
Title : BIOCOPATIBLE ARTICLE

Art Unit : 1773
Examiner : Paulraj, Christopher

#17
K10
8-11-03

MAIL STOP AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

NOTICE OF APPEAL

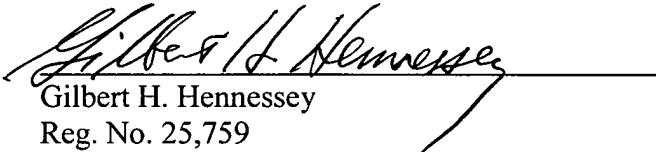
Applicants hereby appeal to the Board of Patent Appeals and Interferences from the action dated January 27, 2003, finally rejecting claims 1-3, 5-11, 17 and 19.

A petition for an extension of time under 37 CFR §1.136 to extend the time to respond to the final rejection for 3 months to and including July 27, 2003 is enclosed.

A check in the amount of \$160 for the appeal fee is enclosed. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: 7/28/03


Gilbert H. Hennessey
Reg. No. 25,759

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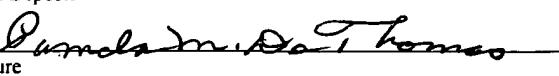
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July 28, 2003

Date of Deposit


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Pamela M. DeThomas

Typed or Printed Name of Person Signing Certificate

07/31/2003 MAHMED1 00000009 09521086

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Miladin P. Lazarov et al.
 Serial No. : 09/521,086
 Filed : March 7, 2000
 Title : BIOCOMPATIBLE ARTICLE

Art Unit : 1773
 Examiner : Paulraj, Christopher

#18
Kw
8-11-03

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 Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

PETITION FOR THREE-MONTH EXTENSION OF TIME

Pursuant to 37 CFR §1.136, applicants hereby petition that the period for response to the action dated January 27, 2003 be extended for three months to and including July 27, 2003.

Enclosed is a check for \$465 for the required fee. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: 7/28/03


 Gilbert H. Hennessey
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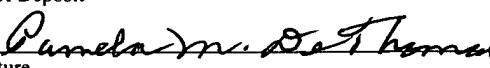
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July 28, 2003

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Pamela M. DeThomas

Typed or Printed Name of Person Signing Certificate

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